

## REMARKS:

Claims 1-23 are pending. Claims 1, 3, 10, 11, 13 and 20 have been amended to more clearly recite the invention. Support for each of these amendments is found, for example, on page 8, lines 15-20 ("In one embodiment, the method of the invention preferably includes detecting hemodynamic parameters corresponding to the motion of a patient's heart with an accelerometer, converting the detected parameters into digital data that is fed into an analysis module for calculation and display of ventricular contraction mapping, and comparing the results generated by different pacemaker lead placement to provide an optimal lead location").

In the International Preliminary Examination Report, the Examiner found claims 1, 2, and 4 to lack novelty, and claims 1-4 and 9 to lack an inventive step, in view of Salo et al. (U.S. Patent No. 5,334,222). Salo et al. disclose a cardiac stimulating apparatus and method, the novelty of which is to "modify the sequence of *pacing* impulses to one or more chambers of the heart in order to optimize the performance of the heart...." and "to determine whether the applied *pacing* sequence is optimal." Summary of the Invention, col. 2, lines 18-29, emphasis added. Thus, the method of Salo et al.'s invention essentially involves optimizing paced cardiac function by comparing different AV delay time intervals between beats stimulated by a programmable cardiac pacemaker.

In contrast, the amended claim 1 of the present invention recites, in relevant part, the steps of:

- motion (a) collecting seismocardiographic (SCG) data corresponding to heart during paced beats of said patient's heart;
- motion (b) collecting seismocardiographic (SCG) data corresponding to heart during un-paced beats of said patient's heart;
- steps (a) and (c) determining a hemodynamic parameter based on the SCG data of (b); and
- said (d) determining whether cardiac performance is improved by comparing hemodynamic parameter generated by step (a) with that generated by step (b). (emphasis added)

The applicants respectfully submit that the invention as embodied in claim 1 is distinguishable from the cited reference, in that determining whether cardiac performance is improved by comparing hemodynamic parameters generated during

both paced and un-paced beats of a patient's heart is not disclosed or suggested by Salo et al. Indeed, all that the cited patent actually discloses is "Once the AV delay value has been incremented by [the programmed quantity N], the associated cardiac function is measured (block 116)...." (col. 7, lines 46-48). In other words, for a given AV delay value, block 116 represents the measurement of paced cardiac function; it does not represent whether pacing shows improved cardiac function as compared with the un-paced state.

Furthermore, to the extent any comparison is described by Salo et al., it is a comparison of different pacing rhythms caused by variance of the pacemaker's AV delay setting, not a comparison of cardiac performance based on paced and un-paced cardiac beats (see col. 7, lines 46-51: "Once the AV delay value has been incremented by [the programmed quantity N], the associated cardiac function is measured (block 116) and a test is made at block 118 to determine whether the newly measured cardiac function parameter exceeds the same parameter measured on an earlier cycle....").

It also should be noted that Salo et al. use an accelerometer to measure heart sounds (col. 5, lines 22-23). Thus, the Salo et al. patent teaches the measurement of heart sounds by an accelerometer (as well as cardiac impedance through an appropriate sensor) to determine optimal AV delay. These sensors are intracardiac sensors and the circuitry is designed to provide a closed loop circuit to automatically adjust AV delay. In contrast, the present invention utilizes accelerometer sensors applied to the body externally to measure cardiac vibrations using the low frequency (sub audible) end of the spectrum (typically below 35 hz) to measure the acceleration of the heart walls as this motion is transmitted to the body surface. Using the method and apparatus of the invention, the applicants thus can identify onset times for mitral and aortic openings and closings and for tricuspid and pulmonary openings and closings. This is not possible from using an accelerometer as taught by Salo et al. to measure heart sounds. Therefore, to the extent that the Examiner believes that there is any disclosure in Salo et al. that renders the present invention obvious, the applicant respectfully traverses.

Moreover, it is the accurate identification and measurement of these valvular events that allows the applicants to calculate various indices of cardiac function. The more

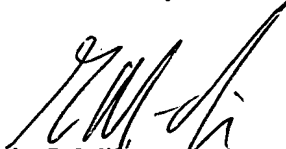
important of these include: left ventricular isovolumetric contraction time (IVCT), the time from MC (mitral opening) to AO (aortic opening), left ventricular isovolumetric relaxation time (IVRT), the time from aortic closure (AC) to mitral opening (MO), and myocardial performance index (MPI). Salo et al. teach nothing about the measurement, comparison, or calculation of these hemodynamic parameters based on both paced and un-paced heart motion. Therefore, none of the amended claims is believed to be anticipated or an obvious extension of this reference.

In view of the foregoing, the applicant respectfully requests that the Examiner reconsider the rejections made in the International Preliminary Examination Report and render a decision of patentability in the present case.

No fee is believed to be due with this amendment. Please charge any unforeseen costs to our Deposit Account No. 17-0055.

Respectfully submitted,

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